

Application No. 10/092,934  
 Amendment dated 8/30/05  
 After Final Office Action of 6/1/05

Docket No.: 022719-0023RCE

# **REMARKS**

The pending Office Action addresses claims 1-40, rejecting claims 1, 3, 7, 8, 10, 11, 14-17, 19, 20, 22, 25, and 28-40. Claims 2, 4-6, 9, 12, 13, 18, 21, 23, 24, 26, and 27 were withdrawn from consideration.

## ***Claim Rejections under 35 U.S.C. § 102***

***(1) U.S. Patent No. 5,569,186 of Lord, et al.***

Claims 1, 3, 10, 11, 15, 17, and 28-39 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,569,186 of Lord et al.

Claim 1 recites an implantable drug delivery system. The system comprises an infusion pump including a fluid outlet and a fluid delivery line effective for extending from the fluid outlet to a discharge portion positionable at a target tissue site. Further, a controlled release drug assembly is positioned downstream from the infusion pump. The drug assembly is configured for controllably releasing drug material and communicating with the fluid delivery line so the drug material is released into the fluid delivery line. The pump assembly is effective to deliver a carrier fluid to the fluid outlet so the drug material released into the delivery line discharges at the discharge portion to treat the target tissue site. Likewise, independent claim 29 also recites that the implantable drug release assembly is in communication with the fluid delivery line and is downstream from the infusion pump.

Lord does not teach or suggest a controlled release drug assembly positioned *downstream* from an infusion pump. Rather, as shown, for example, in FIG. 1 of Lord, a pump containing insulin for release into a patient communicates with a sensor through radio telemetry (or a cable as shown in FIG. 4) to control the insulin release. The system described in Lord merely houses insulin within an infusion pump and delivers an appropriate dose to the patient without the need for a carrier fluid. There is no suggestion in Lord of an infusion pump with a drug assembly positioned downstream.

Additionally, Lord does not teach a fluid delivery line extending from a fluid outlet to a discharge portion *positionable at a target tissue site*. As shown in FIG. 1, catheter 22, which

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delivers insulin to a patient, is not positioned at a target tissue as recited in the independent claims of the invention. Instead, Lord teaches that medication is delivered systemically to a patient through catheter 22 which discharges the insulin near the site of the infusion pump. There is no suggestion of positioning catheter 22 at a target tissue site in the teachings of Lord.

Accordingly, claims 1 and 29, and dependent claims 3, 10, 11, 15, 17, and 28 which depend from claim 1, and claims 30-39 which depend from claim 29, distinguish over Lord.

*(2) U.S. Publication No. 2004/0034332 of Uhland*

Claims 1, 3, 7, 8, 10, 11, 14-17, 19, 20, 22, 25, and 28-40 are rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by U.S. Publication No. 2004/0034332 of Uhland.

Uhland discloses a microchip device containing reservoirs of molecules for release that, in one application, can be implanted into a patient as part of a micropumping system such as the one disclosed in U.S. Patent No. 4,596,575 of Rosenberg (See paragraphs 108 and 109 of Uhland). Independent claims 1, 29 and 40 of the pending application recite that the fluid delivery line extends from the fluid outlet to a discharge portion *positionable at a target tissue site*. Neither Uhland nor Rosenberg teach or suggest this feature of the claimed invention. Instead of a discharge portion positioned at a target tissue, the fluid from the micropump is released at a position proximate to the micropump itself and diffused through the body. Uhland and Rosenberg thus fail to disclose or suggest release at the site of a target tissue. Accordingly, independent claims 1, 29 and 40, and claims 3, 7, 8, 10, 11, 14-17, 19, 20, 22, 25, and 28 which depend on claim 1 and claims 30-39 which depend on claim 29, distinguish over Uhland.

*Claim Rejections under 35 U.S.C. § 103*

Claims 7, 8, 14, 19, 20, 22, and 25 are rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Lord in further view of U.S. Patent No. 5,797,898 of Santini et al. As explained above, independent claim 1 distinguishes over Lord and represents allowable subject matter. Claims 7, 8, 14, 19, 20, 22, and 25, which depend from claim 1, therefore distinguish over Lord at least because they depend from an allowable base claim. Further, Santini does not remedy the deficiencies of Lord – namely, Santini does not teach a fluid delivery line that is positioned at a target tissue site. Thus, claims 7, 8, 14, 19, 20, 22, and 25, which depend from

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claim 1, therefore distinguish over Lord in combination with Santini at least because they depend from an allowable base claim.

**Conclusion**

In view of the above, Applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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